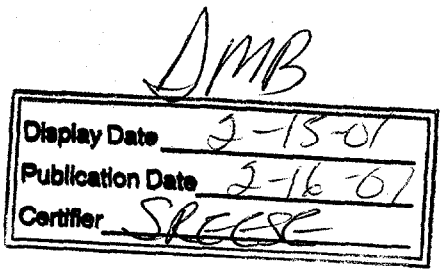
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration



[Docket No. 00D–1316]

Guidance for Industry on How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final guidance for industry (#88) entitled. "How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation" in the Center for Veterinary Medicine (CVM). This final guidance provides guidelines to new animal drug sponsors (sponsors) on how to submit a request for a meeting or teleconference about a new animal drug submission as an e-mail attachment by Internet. These electronic submissions are part of CVM's ongoing initiative to provide a method for paperless submissions. This final guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments at any time.

ADDRESSES: Copies of the final guidance document entitled "How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation" may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/. Persons without Internet access may submit written requests for single copies of the final guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

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Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the final guidance document and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 29, 2000 (65 FR 40108), FDA published the notice of availability of the draft guidance entitled "How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation" giving interested persons until August 28, 2000, to submit comments. FDA received no comments.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the Electronic Records; Electronic Signatures, final regulation. This regulation (21 CFR part 11) provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. This final rule also established public docket number 97S–0251 to provide a permanent location for a list of the documents or parts of documents that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. CVM will identify in this public docket the types of documents that may be submitted in electronic form as those documents are identified in final guidance or regulations. This docket is accessible on the Internet at http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm.

The electronic submission of requests for meetings and teleconferences is part of CVM's ongoing initiative to provide a method for paperless submissions. The final guidance implements provisions of the GPEA. The GPEA of 1998 (Public Law 105–277) requires Federal agencies,

by October 21, 2003, to provide: (1) For the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.

On request, CVM will hold meetings and/or teleconferences to assist sponsors with new animal drug submissions and general questions. Currently, sponsors submit meeting and teleconference requests to CVM on paper. CVM would like to allow sponsors to request meetings and teleconferences in a manner more efficient and time saving to them. This final guidance will give sponsors the option to submit a request for a meeting or teleconference as an e-mail attachment by the Internet.

Before submitting requests for meetings or teleconferences by e-mail, sponsors should first register and follow the instructions in the final guidance for industry (#108) entitled "How to Use E–Mail to Submit Information to CVM."

II. Significance of Guidance

This Level 1 final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The final guidance represents the agency's current thinking on submitting a request for a meeting or teleconference about new animal drug submissions by e-mail. The final guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

In the document announcing the availability of the draft version of this guidance (65 FR 40108), FDA published notice of the proposed collection of information related to the guidance. The **Federal Register** document also requested comments on the burden estimates for the guidance document. No comments were received on the estimated annual reporting burden. The annual reporting burden estimate of 116 hours, therefore remains unchanged. In the **Federal Register**

of September 21, 2000 (65 FR 57194), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this final guidance document have been approved under OMB control number 0910–0452. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. This approval expires November 30, 2003.

V. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this final guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 9, 2001

Ann M. Witt,
Acting Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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